NOTICES OF SUPPLEMENTAL PROPOSED RULEMAKING

After an agency has filed a Notice of Proposed Rulemaking with the Secretary of State's Office for *Register* publication and the agency decides to make substantial changes to the rule after it is proposed, the agency must prepare a Notice of Supplemental Proposed Rulemaking for submission to the Office, and the Secretary of State shall publish the Notice under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.). Publication of the Notice of Supplemental Proposed Rulemaking shall appear in the *Register* before holding any oral proceedings (A.R.S. § 41-1022).

NOTICE OF SUPPLEMENTAL PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES HEALTH CARE INSTITUTIONS: LICENSING

PREAMBLE

1. Register citation and date for the original Notice of Proposed Rulemaking:

Notice of Proposed Rulemaking: 9 A.A.R. 1914, June 20, 2003

<u>2.</u>	Sections Affected	Rulemaking Action
	R9-10-201	Amend
	R9-10-203	Amend
	R9-10-204	Amend
	R9-10-206	Amend
	R9-10-207	Amend
	R9-10-208	Amend
	R9-10-209	Amend
	R9-10-212	Amend
	R9-10-213	Amend
	R9-10-218	Amend
	R9-10-219	Amend
	R9-10-220	Amend
	R9-10-222	Amend
	R9-10-229	Amend
	R9-10-230	Amend

3. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 36-132(A) and 36-136(F) Implementing statutes: A.R.S. §§ 36-405 and 36-406

4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Kathy McCanna, Program Manager

Address: Arizona Department of Health Services

150 N. 18th Avenue, Suite 450

Phoenix, AZ 85007

Telephone: (602) 364-2841 Fax: (602) 364-4764

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Notices of Supplemental Proposed Rulemaking

E-mail: kphilli@hs.state.az.us

5. An explanation of the rules, including the agency's reasons for initiating the rules:

A.R.S. § 36-405(A) requires the Director of the Arizona Department of Health Services (Department) to adopt rules establishing minimum standards and requirements for the construction, modification, and licensure of health care institutions necessary to assure the public health, safety, and welfare. It further requires that the rules include standards and requirements consistent with generally accepted practices of health care relating to construction; equipment; sanitation; staffing for medical, nursing, and personal care services; and recordkeeping pertaining to the administration of medical, nursing, and personal care services. A.R.S. § 36-405(B) allows the Department, by rule, to classify and subclassify health care institutions according to character, size, and range of services provided.

The Department recently made new rules regulating hospitals, a classification of health care institutions. The new rules took effect October 1, 2002. During training on and implementation of the new rules, the Department and stakeholders identified areas that require technical or clarifying changes. The purpose of this rulemaking is to make those technical or clarifying changes and any other changes determined necessary. The Department established a task force to review and discuss these changes. The task force consisted of individuals who had been involved with the task force for the 2002 rulemaking and stakeholders representing the areas of expertise related to the rule changes. During the course of the review and discussions, several new issues were identified. These have also been incorporated into this rulemaking.

6. An explanation of the substantial change which resulted in this supplemental notice:

In R9-10-201, the Department is adding a definition for the term "active tuberculosis" because that term in now used in R9-10-229.

In response to public comment, the Department is adding a definition for the term "acuity plan" in R9-10-201 and deleting the definition for the term "patient classification system," which was added in the original Notice of Proposed Rulemaking. Based on public comment, the term "patient classification system" has a negative connotation suggesting an inflexible, complicated system of patient assessment for determining staffing needs. Commenters suggested using the term "acuity plan," which has a more positive connotation. Accordingly, the term "acuity plan" was added using the same language that was used previously for "patient classification system."

In R9-10-201, the Department is adding a definition for the term "approved test for tuberculosis" because that term in now used in R9-10-229.

In response to public comment, the Department is changing the definition of "order" in R9-10-201 of the proposed rules to include language that was deleted in the original Notice of Proposed Rulemaking. This language clarifies the types of individuals who may write orders for patients requiring hospital services.

In R9-10-201, the Department is adding a definition for the term "symptoms suggestive of tuberculosis" because that term in now used in R9-10-229.

In R9-10-203(C)(2)(b), the Department is adding language to specify that a hospital administrator's responsibility for enacting policies and procedures covering acuity includes obtaining sufficient nursing personnel to meet the needs of patients at all times.

In response to public comment, the Department is deleting R9-10-203(C)(1)(h) from the original Notice of Proposed Rulemaking, which required that a hospital administrator be responsible for enacting policies and procedures that cover how the hospital addresses each occurrence of exceeding licensed capacity. In addition, the Department is deleting R9-10-203(C)(5)(c) from the original Notice of Proposed Rulemaking, which required that the action taken for resolving each occurrence of exceeding capacity be documented and maintained on the premises for 12 months from the date of the occurrence. Commenters believed this requirement to be burdensome and with little added benefit. As an alternative, commenters suggested that the issue of overcapacity be addressed in the context of quality management. Accordingly, the Department has added a new provision in R9-10-204(B)(1), which requires the administrator to enact a plan that includes a method to identify, document, and evaluate occurrences of exceeding licensed capacity, as described in R9-10-203(C)(5), and a method to document the actions taken for resolving occurrences of exceeding licensed capacity.

In R9-10-204, the Department is also adding a new subsection (B)(3), which states that the administrator shall require that the acuity plan in R9-10-208(C)(2) be reviewed and evaluated every 12 months and that the results be documented and reported to the governing authority.

For consistency, the Department is deleting the term "patient classification system" in R9-10-206 and R9-10-208 and inserting the term "acuity plan."

In response to public comment, the Department is revising the proposed R9-10-206(2) by changing the phrase "for each unit **or** population type" to read: "for each unit **and** population type." The Department is making this change to ensure that the rule requires personnel to demonstrate competency based on criteria established for both the patient population-type and the type of unit to which the personnel member is assigned.

For consistency, the Department is revising R9-10-206(3) by replacing text in the original rules and the Notice of Proposed Rulemaking with language using the defined term "approved test for tuberculosis," found in R9-10-201.

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As discussed above, the Department is also revising R9-10-207(3) by replacing text with language using the defined term "approved test for tuberculosis."

The Department is substantially revising R9-10-208(C)(2) to incorporate changes suggested by commenters. First, R9-10-208(C)(2) is being revised to retain the current requirement that an acuity plan be documented, in addition to being established and implemented, as the original Notice of Proposed Rulemaking states. Second, the acuity plan must meet the requirements listed in new subsections (C)(2)(a), (b), and (c). Under subsection (C)(2)(a), the acuity plan must include a method that establishes the types and numbers of nursing personnel that are required for each unit in the hospital. Under subsection (C)(2)(b), the acuity plan must include an assessment of a patient's need for nursing services, made by a registered nurse providing direct nursing services. Under subsection (C)(2)(c), the acuity plan must also include a policy and procedure stating the steps a hospital will take to obtain the nursing personnel necessary to meet patient acuity.

In response to public comment, the Department is revising the proposed R9-10-208(C)(3), which required that a hospital verify the validity and reliability of the patient classification system for each unit every 12 months from the date of implementation. Commenters suggested that using the terms "validity and reliability" implied a statistical analysis requirement, which could be complicated and costly. The Department revised the language of R9-10-208(C)(3) to hold a nurse executive responsible for requiring that registered nurses be knowledgeable about and implement the acuity plan required under R9-10-208(C)(2).

In response to public comment, the Department is revising the proposed R9-10-208(C)(4) by changing the phrase "If licensed capacity...is exceeded **and** patients are kept in areas without licensed beds" to read: "If licensed capacity...is exceeded **or** patients are kept in areas without licensed beds." The Department is making this change to ensure that the provision applies in either situation. In addition, the Department is deleting a reference to a patient classification system and adding a provision requiring that nursing personnel be assigned according to the specific rules for the organized service in this Chapter. This change is intended to clarify that when a patient is temporarily held in an area of the hospital such as an Emergency Department, nursing personnel are to be assigned according to the staffing requirements for the type of unit to which the patient will eventually be transferred.

For purposes of consistency, the Department is revising R9-10-220(B)(5)(b) by deleting the term "patient classification system" and inserting the term "acuity plan" in its place.

The Department is revising R9-10-220(B) to require that a registered nurse qualified in advanced cardiopulmonary resuscitation specific to the age of the patient be responsible for the patient requiring intensive care services for purposes of performing resuscitation. This change is intended to clarify that registered nurses and other personnel who are not qualified in advanced cardiopulmonary resuscitation may be responsible for providing hospital services other than resuscitation to that patient.

In R9-10-229(A), the Department is revising the requirements for tuberculosis control in a hospital to require annual screening only for those hospitals that have a heightened risk of tuberculosis transmission due to the number of patients with infectious active tuberculosis admitted during the previous calendar year. For purposes of consistency and clarity in the revised requirements, the Department now uses the newly defined term "approved test for tuberculosis." The rule also establishes separate requirements for individuals with a documented history of a positive result from an approved test for tuberculosis and a requirement for post-exposure testing. The Department is making these changes in response to public comment and anticipated changes in the Centers for Disease Control and Prevention recommendations for tuberculosis control, which are expected to be published early in 2004.

Finally, the Department has made numerous changes to make the rules more clear, concise, and understandable.

7. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

The Department estimates the overall economic impact for this rulemaking to be minimal to moderate, with the benefits of clear and concise rules outweighing the costs. Most of the changes to the new rules are technical and clarifying in nature and should not pose an economic impact on the hospitals. The requirements already established in rule should have little or no economic impact on the hospitals as the language is being changed only for clarification purposes. New requirements designed to improve the delivery of hospital services and increase the efficiency of the regulatory process should also have a minimal-to-moderate economic impact on the hospitals.

Although the Department has changed the requirements for tuberculosis (TB) screening for all personnel and medical staff members, the overall economic impact to the hospitals is expected to decrease. The new TB requirements will simplify the TB screening process for the hospitals and are based on anticipated changes forthcoming from the Centers for Disease Control and Prevention (CDC) guidelines expected to be published later this year. The new TB requirements take into consideration the overall number of TB cases admitted to a hospital each calendar year. From an infection control standpoint, it makes good sense that the individuals working in a hospital with a higher number of TB cases are at an increased risk of exposure and should be screened more frequently than individuals working at a hospital with few, if any, admitted cases. When this new scheme was proposed to the task force members, there was a consensus that this approach to TB screening is appropriate. In addition, the Department has broadened the types of testing acceptable for tuberculosis evaluation. This change provides for updating of tuberculosis testing by allowing

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use of testing procedures that are consistent with the recommendations of the Centers for Disease Control and Prevention or the tuberculosis control officer.

During the course of the Department's training on and subsequent implementation of the new rules, it became evident that a number of hospitals are still unclear about the requirement for an acuity plan and the purpose of an acuity plan. After spending a considerable amount of time discussing acuity plans, the Department determined that the rules should be changed to clarify that acuity plans must determine the staffing requirements based on the specific needs of the patients. Through this process, the Department learned that a number of hospitals continue to staff units based on budgetary constraints or the number of staff scheduled for a given shift rather than based on patient acuity. The Department is making changes to the rules for clarification. The rule changes pertaining to this requirement should not pose an additional economic impact to the hospitals because they are not new requirements, just clarifications.

The Department is also changing the staffing ratio requirement for an intensive care services (ICU) environment. The Department received criticism from a number of direct care nurses concerning the staffing ratio of one nurse to three patients in an ICU. At the time of the 2002 rulemaking, the Department made a commitment to revisit this requirement after the new rules became effective. The Department has determined that the national standard is one nurse to two patients in an ICU and is changing the rule to reflect that standard. The task force members agreed that 1:2 is the national standard, but were concerned about situations that could lead to a hospital's periodic noncompliance such as restroom breaks, lunch breaks, assignment to the hospital's trauma team, or transporting a patient for a diagnostic test. Typically, the unit covers for these instances by having other ICU nurses, or a team leader or nurse manager who does not have a patient assignment, monitor the absent nurse's patients. The language in the rule clarifies that there must be a minimum of one nurse assigned to every two patients in the ICU. Temporary absences by nursing staff for those reasons mentioned above would not violate the rule if there is a 1:2 assignment. The hospital must have policies and procedures to determine how it will ensure the health and safety of the ICU patients at all times. The change in this requirement should not result in an increased economic impact for those hospitals that utilize a 1:2 staffing ratio in the ICU environment, which the Department understands is the majority of hospitals. There may be an increased economic impact to rural hospitals that have an ICU. If a rural hospital provides intensive care services, the rural hospital must provide the same standard of care as any other hospital providing that level of service.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Kathy McCanna, Program Manager

Address: Arizona Department of Health Services

150 N. 18th Avenue, Suite 450

Phoenix, AZ 85007

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or

Name: Kathleen Phillips, Rules Administrator

Address: Arizona Department of Health Services

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Phoenix, AZ 85007

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E-mail: kphilli@hs.state.az.us

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rules, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rules:

The Department has scheduled the following oral proceedings:

Date: January 16, 2004

Time: 10:00 a.m.

Location: Arizona Department of Health Services

1740 W. Adams, Room 411

Phoenix, AZ 85007

A person may submit written comments on the proposed rules no later than the close of record, 5:00 p.m., January 16, 2004, to either of the individuals listed in items #4 and #9.

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A person with a disability may request a reasonable accommodation, such as a sign language interpreter, by contacting one of the persons listed in items #4 and #9. Requests should be made as early as possible to allow time to arrange the accommodation.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. A reference to any study relevant to the rules that the agency reviewed and either proposes to rely on in its evaluation of or justification for the rules or proposes not to rely on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department has read numerous studies and reports from commenters addressing R9-10-220(B)(5)(a), which requires intensive care units (ICUs) to be staffed with a minimum of one registered nurse assigned for every two patients. These studies and reports may be categorized in three general categories: (1) supports the 1:2 ICU staffing ratio, (2) neutral or identifies both positive and negative aspects of the 1:2 ICU staffing ratio, and (3) opposes the 1:2 ICU staffing ratio. The studies and reports listed below are grouped accordingly.

Supports the 1:2 ICU Staffing Ratio

The Department is relying on the information in the following reports and studies as support for the 1:2 nurse-staffing ratio for patients requiring intensive care services:

Justin B. Dimick et al., "Effect of Nurse-to-Patient Ratio in the Intensive Care Unit on Pulmonary Complications and Resource Use After Hepatectomy," *American Journal of Critical Care* 376 (Nov. 2001), available at http://www.aacn.org/882565f400622f2c.nsf;

Deborah Dang et al., "Postoperative Complications: Does Intensive Care Unit Staff Nursing Make a Difference?" 31 *Heart & Lung: the Journal of Acute And Critical Care* 219 (May/June 2002), available at http://www.mosby.com/hrtlng;

Jerome Robert et al., "The Influence of the Composition of the Nursing Staff on Primary Bloodstream Infection Rates in a Hospital Intensive Care Unit," *Infection Control and Hospital Epidemiology* 12 (Jan 2000), available by writing to the Managing Editor, 6900 Grove Road, Thorofare, NJ 08086-9447 or by calling (856) 848-1000;

Scott K. Fridkin et al., "The Role of Understaffing in Central Venous Catheter-Associated Bloodstream Infections," 17 *Infection Control and Hospital Epidemiology* 150 (Mar. 1996), available by writing to the Managing Editor, 6900 Grove Road, Thorofare, NJ 08086-9447, or by calling (856) 848-1000;

Stephan Harbarth et al., "Outbreak of Enterobacter Cloacae Related to Understaffing, Overcrowding, and Poor Hygiene Practices," 20 *Infection Control and Hospital Epidemiology* 598 (Sept. 1999), available by writing to the Managing Editor, 6900 Grove Road, Thorofare, NJ 08086-9447, or by calling (856) 848-1000;

Lennox K. Archibald et al., "Patient Density, Nurse-to-Patient Ratio and Nosocomial Infection Risk in a Pediatric Cardiac Intensive Care Unit," 16 *Pediatric Infectious Disease Journal* 1045 (Nov. 1997), available at http://www.pidj.com;

Peter J. Pronovost et al, "Organizational Characteristics of Intensive Care Units Related to Outcomes of Abdominal Aortic Surgery," 281 *JAMA* 1310 (Apr. 14, 1999), available at http://www.jama-assn.org/cgi/content/abstract/281/14/1310?;

Jean-Benoit Thorens et al., "Influence of the Quality of Nursing on the Duration of Weaning from Mechanical Ventilation in Patients with Chronic Obstructive Pulmonary Disease," 23 *Critical Care Medicine* 1807 (Nov. 1995), available at http://www.ccmjournal.com;

Janet Tucker et al., "Patient Volume, Staffing, and Workload in Relation to Risk-Adjusted Outcomes in a Random Stratified Sample of UK Neonatal Intensive Care Units: A Prospective Evaluation," 359 *The Lancet* 99 (Jan, 12, 2002), available at http://www.thelancet.com/search/search.isa;

Linda H. Aiken, "Hospital Nurse Staffing and Patient Mortality, Nurse Burnout, and Job Dissatisfaction," 288 *JAMA* (Oct. 23, 2002), available at: http://jama.ama-assn.org/cgi/content/abstract/288/16/1987;

Peter J. Provost et al., "Intensive Care Unit Nurse Staffing and the Risk for Complications After Abdominal Aortic Surgery," *American College of Physicians* (Sept/Oct. 2001), available at http://www.acponline.org/journals/ecp/sepoct01/pronovost.htm;

Linda H. Aiken, "More Nurses, Better Patient Outcomes: Why Isn't It Obvious?" *American College of Physicians* (Sept./Oct. 2001), available at http://www.acponline.org/journals/ecp/sepoct01/aiken.htm;

Barbara Tone, "Nurse-Patient Ratios, Professionalism, and Safety," *Nurseweek* (May 3, 1999), available at http://www.nurseweek.com/features/99-5/ratios.html;

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American Association of Homes and Services for the Aging, "CMS Study: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes," in *AAHSA Health Policy Bulletin* (Mar. 7, 2002), available at http://www.aahsa.org/member/healthbulletins/hb030702.asp;

Letter from Kay McVay, President, California Nurses Association, to California Dep't of Health Services Office of Regulations (July 17, 2003), available by writing to California Nurses Association, 2000 Franklin St., Oakland, CA 94612, or by calling (510) 273-2200; and

California Nurses Association, "Title 22 – 1996 Revisions to Nursing Services Regulations," in *California Nurse* (April, year not indicated), available at http://www.calnurses.org/cna/cal/april/t22.htm.

Neutral or Identifies Positive and Negative Aspects of the 1:2 ICU Staffing Ratio

The Department has considered the information in the following reports and studies related to the 1:2 nurse-staffing ratio for patients requiring intensive care services:

Jean Ann Seago, "Nurse Staffing, Models of Care Delivery, and Interventions," in *Making Health Care Safer: A Critical Analysis of Patient Safety Practices* at 423 (July 20, 2001), available at http://www.ahcpr.gov/clinic/ptsafety/pdf/chap39.pdf;

Barbara Tone, "New Law on Nurse-Patient Ratios Draws Mixed Reaction," *NurseWeek* (Oct. 18, 1999), available at http://www.nurseweek.com/news/99-10/51a.html;

Janet M. Coffman et al., "Minimum Nurse-to-Patient Ratios In Acute Care Hospitals In California," 21 *Health Affairs* 53 (Sept.,/Oct. 2002), available at www.healthaffairs.org;

Linda Burnes Bolton et al., "A response to California's Mandated Nursing Ratios," *Journal of Nursing Scholarship* 179 (Second Quarter, 2001), available at http://www.journalofnursingscholarship.org;

"ANA: Nurse-To-Patient Ratios Proposal Will Strengthen Patient-Care Safety Net, But Broader Solutions Still Needed," *Nevada Nurses Association* (Jan. 23, 2002), available at http://www.nvnurses.org/CA_ratio_ANA_pressrelease.htm;

"ANA: Nurse-To-Patient Ratios Proposal Will Strengthen Patient-Care Safety Net, But Broader Solutions Still Needed," *Nursing World* (Jan. 23, 2002), available at http://www.nursingworld.org/pressrel/2002/pr0123.htm;

"California Proposes Nurse Staffing Limits," *USA Today* (Jan. 23, 2002), available at http://www.usatoday.com/news/health/2002-01-23-nurse-ratios.htm;

"California's New Nurse Staffing Mandate Highlights Crisis in Nurse Staffing Nationally," *American Nurses Association* (Oct. 13, 1999), available at http://www.needlestick.org/pressrel/1999/pr1013.htm; and

"Nurse Staff Ratios," California Healthcare Association (2003), available at http://www.calhealth.org/public/edu/gms/NurseStaffRatios.html.

Opposes the 1:2 ICU Staffing Ratio

The Department has considered the information in the following report, but is not relying on the report's evaluation of the 1:2 nurse-staffing ratio for patients requiring intensive care services:

"PSNA Chooses Not to Support Proposed Staffing Ratio Legislation," *Pennsylvania Nurses Association* (June 6, 2003).

14. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES HEALTH CARE INSTITUTIONS: LICENSING

ARTICLE 2. HOSPITALS

Section	
R9-10-201.	Definitions
R9-10-203.	Administration
R9-10-204.	Quality Management
R9-10-206.	Personnel
R9-10-207.	Medical Staff
R9-10-208.	Nursing Services
R9-10-209.	Patient Rights
R9-10-212.	Transport
R9-10-213.	Transfer
R9-10-218.	Clinical Laboratory Services and Pathology Services

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R9-10-219. Radiology Services and Diagnostic Imaging Services R9-10-220. Intensive Care Services R9-10-222. Perinatal Services R9-10-229. Infection Control R9-10-230. **Environmental Services**

ARTICLE 2. HOSPITALS

R9-10-201. **Definitions**

- No change
- "Active tuberculosis" has the same meaning as in A.R.S. § 36-711.
- 2.3. No change
- 3.4. "Acuity" means a determination of the level and type of nursing services, based on the patient's illness or injury, that are required to meet the needs of the patient a patient's need for hospital services based on the patient's medical condition.
- "Acuity plan" means a method for establishing nursing personnel requirements by unit based on a patient's acuity.
- 4.6. No change
- 5.7. No change
- 6.8. No change
- 7.9. No change
- 8.10.No change
- 11. "Approved test for tuberculosis" means a Mantoux skin test or other test for tuberculosis recommended by the Centers for Disease Control and Prevention or the tuberculosis control officer.
- 9-12. "Assessment" means an analysis of a patient's <u>current medical condition and</u> need for hospital services.
- 10.13.No change
- 14. "Attending physician's designee" means a physician, a physician assistant, a registered nurse practitioner, or a medical staff member who has clinical privileges and is authorized by medical staff bylaws to act on behalf of the attending physician.
- 11.15.No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
- 12.16. No change
 - a. No changeb. No change

 - c. No change
- 13.17. No change
- 14.18. No change
- 15.19.No change
- 16.20. No change
- 17.21. No change
- 18.22. No change
- 19.23. No change
- 20.24. No change
- 21.25. No change
- 26. "Critically ill inpatient" means an inpatient whose severity of medical condition requires the nursing services of specially trained registered nurses for:
 - Continuous monitoring and multi-system assessment,
 - b. Complex and specialized rapid intervention, and
 - c. Education of the patient or patient's representative.
- 27. "Couplet care" means services provided to a mother and neonate while the neonate is housed with the mother in the mother's room.
- 22.28. No change
- 23.29. No change
- 24.30. No change
- 25.31. No change
- 26.32.No change
- 27.33. No change
- 28.34. No change

- 29.35. No change 30.36. No change 31.37. No change 32.38. No change 33.39. No change 34.40. No change 35.41. No change 36.42. No change 37.43. No change 38.44. No change 39.45. No change 40.46. No change 41.47. No change 42.48. No change 43.49. No change 44.50. No change 45.51. No change 46.52. No change 47.53. No change 48.54. No change
- 49.55. No change 50.56. No change
- 51.57. No change
- a. No change
 - b. No change
- 52.58.No change
- 53.59. "Intensive care services" means hospital services provided to an a critically ill inpatient who requires the services of specially trained nursing and other personnel members as specified in hospital policies and procedures.
- 54.60.No change
- 55.61. No change
 - a. No change
 - b. No change
- 56.62.No change
- 57.63. No change
- 58.64.No change
- 59.65. No change
- 60.66. No change 61.67. No change
- 62.68. No change
- 63.69.No change
- 64.70.No change
 - a. No change
 - b. No change
- 65.71.No change
- 66.72.No change
- 67.73. No change
- 68.74.No change
- 69.75. No change 70.76. No change
- 71.77. No change
- 72.78.No change
- 73-79. "Order" means an instruction to provide medical services, as authorized by the governing authority, to a patient by:
 - a. A medical staff member;
 - b. An individual licensed under A.R.S. Title 32 or authorized by a hospital within the scope of the individual's license; or
 - c. A physician who is not a medical staff member.
- 74.80.No change
- 75.81.No change
- 76.82.No change
 - a. No change

- b. No change
- 77.83. No change
- 78.84.No change
- 79.85. No change
- 80.86. No change
- 81.87. No change
- 82.88.No change
- 83.89. No change
- 84.<u>90.</u>No change
- a. No change
 - b. No change
- 85.91.No change
- 86.92. No change
- 87.93. No change
- 88.94. No change
- 89.95. No change
- 90.96. No change
- 91.<u>97.</u>No change
- 92.98. No change
- 93.99. No change
- 94.100.No change
- 95.101. No change
- 96.102. No change
- 97.103. No change
- 98.104.No change
- 99.105. No change
- 100.106. No change
- 101.107.No change
- 102.108. No change
- 103.109. No change
- 104.110. No change
- 105.111. No change
 - a. No change
- b. No change 106.112. No change
- 107.113.No change
- 108.114. No change
 - a. No change
 - b. No change
 - c. No change
- 115. "Symptoms suggestive of tuberculosis" means any of the following that cannot be attributed to a disease or condition other than tuberculosis:
 - a. A productive cough that has lasted for at least three weeks;
 - b. Coughing up blood; or
 - c. A combination of at least three of the following:
 - i. Fever,
 - ii. Chills,
 - iii. Night sweats,
 - iv. Fatigue,
 - v. Chest pain, and
 - vi. Weight loss.
- 109.116. No change
- 110.117. "Transfer" means a hospital discharging a patient and sending the patient to another hospital for inpatient medical services licensed health care institution as an inpatient or resident without the intent intending that the patient will be returned to the sending hospital.
- 111.118.No change
- 112.119. No change
- 113.120."Treatment" means a procedure or method to cure, improve, or palliate an injury, an illness, or a disease a medical condition.
- 121. "Tuberculosis control officer" has the same meaning as in A.R.S. § 36-711.

- 114.122. No change
- 115.123. No change
 - a. No change
 - b. No change
 - c. No change
- 116.124. No change
- 117.125. No change
- 118.126. No change
- 119.127. No change

R9-10-203. Administration

- **A.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - a. No change
 - b. No change
 - 4. No change
 - 5. No change
 - 6. No change
 - 7. No change
 - 8. No change
 - 9. No change
 - 10. No change
 - 11. No change
 - 12. No change
 - 13. No change
- **B.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- C. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. <u>Include how a personnel member may submit a complaint relating to patient care:</u>
 - d.e. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - e.f. No change
 - f.g. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - g.h. No change
 - h.i. No change
 - i.j. No change
 - <u>j.k.</u> No change
 - k.l. No change
 - 1.m. No change
 - m.n. No change
 - 2. No change
 - a. No change
 - b. Cover acuity, including obtaining sufficient nursing personnel to meet the needs of patients at all times;
 - c. No change
 - d. No change

- e. No change
- f. No change
- g. No change
- h. No change
 - i. No change
 - ii. No change
- i. No change
- j. No change
- 3. No change
- 4. No change
- 5. No change
 - a. No change
 - b. No change
- 6. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
- **D.** No change
 - 1. No change
 - 2. No change

R9-10-204. Quality Management

- **A.** No change
 - 1. No change
 - 2. No change
- **B.** No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. A method to make changes or take action as a result of the identification of a concern about the delivery of hospital services; and
 - e. A method to identify, document, and evaluate occurrences of exceeding licensed capacity, as described in R9-10-203(C)(5), including the actions taken for resolving occurrences of exceeding licensed capacity; and
 - e.f. No change
 - 2. No change
 - a. An identification of each concern about the delivery of hospital services; and
 - b. Any changes made or actions taken as a result of the identification of a concern <u>about the delivery of hospital services;</u>
 - 3. The acuity plan required in R9-10-208(C)(2) is reviewed and evaluated every 12 months and the results are documented and reported to the governing authority; and
 - 3.4. The reports required in subsection subsections (B)(2) and (3) and the supporting documentation for the report reports are:
 - a. No change
 - b. No change

R9-10-206. Personnel

- 1. No change
- 2. Personnel assigned to provide A personnel member who provides medical services or nursing services demonstrate demonstrates competency and proficiency according to criteria established in hospital policies and procedures for each unit and population type to which the personnel member is assigned;

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- 3. Before the initial date of providing hospital services or volunteer service any patient contact or potential patient contact, a personnel member submits one of the following as evidence of freedom from infectious pulmonary tuberculosis according to the requirements in R9 10 229(A)(4):
 - a. A report <u>Documentation</u> of a negative <u>Mantoux skin test</u> result from an approved test for tuberculosis that includes the date and type of test; or
 - b. If the individual has had a positive Mantoux skin test for tuberculosis, a physician's written A statement written and dated by a physician, physician assistant, or registered nurse practitioner, other than the personnel member submitting the statement, indicating that the individual personnel member is free from infectious pulmonary tuberculosis; or
 - c. A report of a negative chest x-ray;
- 4. If applicable, a personnel member complies with the additional tuberculosis control requirements in R9-10-229;
- 4.5. Orientation occurs within the first 30 days of providing hospital services or volunteer service and includes:
 - a. <u>Informing personnel about Department rules for licensing and regulating hospitals and how the rules may be obtained;</u>
 - Reviewing the process by which a personnel member may submit a complaint about patient care to a hospital;
 and
 - c. information determined Providing the information required by hospital policies and procedures;
- 5.6. No change
 - a. No change
 - b. No change
- 6.7. No change
- 7.8. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
- 8.9. No change
- 9.10.No change
 - a. No change
 - b. No change
 - c. No change
- 10.11. No change
- 11.12.No change
 - a. No change
 - b. No change

R9-10-207. Medical Staff

- A. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. No change
 - 7. No change
 - a. No change
 - b. No change
 - c. No changed. No change
 - d. No changee. No change
 - f. No change
 - g. No change
 - h. No change
 - i. No change
 - j. No change
 - k. No change
 - 1. No change
 - m. No change
 - i. No change
 - ii. No change

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- iii. No change
- 8. No change
- **B.** No change
 - 1. By October 1, 2003, a medical staff member submits one of the following as evidence of freedom from infectious pulmonary tuberculosis according to the requirements in R9-10-229(A)(4):
 - a. A report of a negative Mantoux skin test;
 - b. If the individual has had a positive Mantoux skin test for tuberculosis, a physician's written statement that the individual is free from infectious pulmonary tuberculosis; or
 - e. A report of a negative chest x-ray;
 - 2.1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - 3.2. No change
 - a. No change
 - b. Within 72 hours from the time of the Department's request if the individual is no longer a current medical staff member.
 - 3. A medical staff member submits one of the following as evidence of freedom from infectious pulmonary tuberculosis:
 - a. Documentation of a negative result from an approved test for tuberculosis that includes the date and type of test;
 - b. A statement written and dated by a physician, physician assistant, or registered nurse practitioner, other than the medical staff member submitting the statement, indicating that the medical staff member is free from infectious pulmonary tuberculosis; or
 - c. An attestation that the medical staff member is free from infectious pulmonary tuberculosis that includes:
 - The date and type of approved test tuberculosis or the date of an evaluation by another physician, physician assistant, or registered nurse practitioner; and
 - i. The printed name and signature of the medical staff member submitting the attestation;
 - 4. If a medical staff member submits the attestation in subsection (B)(3)(c), the medical staff member, if requested by the Department or hospital, provides documentation that complies with subsection (B)(3)(a) or (b) within 24 hours after the request; and
 - 5. If applicable, a medical staff member complies with the additional tuberculosis control requirements in R9-10-229.

R9-10-208. Nursing Services

- **A.** No change
 - 1. No change
 - 2. No change
- B. No change
- C. No change
 - 1. No change
 - An acuity plan is established, and documented, to determine the types and numbers of nursing personnel necessary to
 provide nursing services to meet the needs of the patients;
 and implemented that includes:
 - a. A method that establishes the types and numbers of nursing personnel that are required for each unit in the hospital;
 - b. An assessment of a patient's need for nursing services made by a registered nurse providing direct nursing services; and
 - c. A policy and procedure stating the steps a hospital will take to obtain the nursing personnel necessary to meet patient acuity;
 - 3. The acuity plan in subsection (C)(2) is implemented; Registered nurses are knowledgeable about the acuity plan and implement the plan established under subsection (C)(2);
 - 4. If licensed capacity in an organized service is exceeded or patients are kept in areas without licensed beds, nursing personnel are assigned according to the specific rules for the organized service in this Chapter;
 - 4.5. No change
 - 5.6. No change
 - 6.7. No change
 - 7.8. No change
 - 8.9. No change
 - 9.10.No change
 - 10.11. No change
 - 11.12.No change

- 12.13. No change
 - a. No change
 - b. No change
 - c. No change
- 14. Nursing personnel duties are assigned consistent with A.R.S. Title 32, Chapter 15;
- 13.15.No change
- 14.16.No change
- 15.17. No change
- 16.18. No change

R9-10-209. Patient Rights

- **A.** No change
 - 1. No change
 - a. No change
 - b. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - i. The hospital's health care directives policies and procedures Proposed medical procedures, alternatives to the medical procedures, associated risks, and possible complications;
 - ii. No change
 - iii. The hospital's patient grievance policies and procedures, including the telephone number of hospital personnel to contact about grievances, and the Department's telephone number if the hospital is unable to resolve the patient's grievance; and
 - iv. Except as authorized by the Health Insurance Portability and Accountability Act of 1996, proposed involvement of the patient in research, experimentation, or education, if applicable; and
 - Proposed medical procedures, alternatives to the medical procedures, associated risks, and possible complications;
 - 3. An inpatient or inpatient's representative is provided the hospital's health care directives policies and procedures at the time of admission;
 - 4. An outpatient or outpatient's representative is provided the hospital's health care directives policies and procedures:
 - a. Before the performance of any invasive procedure, except phlebotomy for obtaining blood for diagnostic purposes; or
 - b. If the hospital services include a planned series of treatment, at the start of each series;
 - 3.5. No change
 - a. No change
 - b. No change
 - 4.<u>6.</u> No change
 - 5. 7. No change
- **B.** The requirements in subsections (A)(2)(a), (A)(2)(d)(i), (A)(3), and (A)(4) shall not apply in an emergency,

R9-10-212. Transport

- **A.** No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. Specify how a medical staff member explains the risks and benefits of <u>a</u> transport and obtains consent from to the patient or the patient's representative based on the:
 - i. No change
 - ii. No change
 - 2. No change
 - a. Consent for transport by the patient or the patient's representative or why consent could not be obtained;
 - a.b. No change
 - b.c. No change
 - e.d. No change
 - d.e. No change
 - e.f. No change

B. No change

- 1. No change
 - a. No change
 - b. Require an assessment of the patient by a registered nurse or a medical staff member upon arrival of the patient and before the patient is returned to the sending hospital <u>unless the receiving hospital is a satellite facility, as defined in A.R.S. § 36-422, and does not have a registered nurse or a medical staff member at the satellite facility;</u>
 - c. No change
 - d. No change
- 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change

C. No change

R9-10-213. Transfer

A. No change

- 1. No change
 - a. No change
 - b. No change
 - c. Specify how the sending hospital personnel members communicate medical record information that is not provided at the time of the transfer; and
 - <u>d.</u> Specify how a medical staff member explains the risks and benefits of a transfer to the patient or the patient's representative based on the:
 - i. Patient's medical condition, and
 - ii. Mode of transfer;
- 2. Except in an emergency, a medical staff member obtains informed consent for the transfer;
- 3. In an emergency, documentation of informed consent or why informed consent could not be obtained is included in the medical record:
- 4.2. One of the following accompanies the patient during transfer to the receiving hospital:
 - a. No change
 - b. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - vi. No change
 - vii. No change

5.3. No change

- a. Consent for transfer by the patient or the patient's representative, except in an emergency;
- a.b. The acceptance of the patient by and communication with an individual at the receiving hospital health care institution;
- b.c. The date and the time of the transfer to the receiving hospital health care institution;
- e.d. No change
- d.e. No change
- **B.** A sending hospital and a receiving hospital that are licensed at separate locations and have the same Medicare number issued by the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services are exempt from subsections (A)(1)(c), (A)(4) (A)(2) and (A)(5)(a) (A)(3)(a).

R9-10-218. Clinical Laboratory Services and Pathology Services

- 1. No change
- 2. No change
- 3. No change
- 4. A special hospital whose patients' diagnoses or treatment requires patients require clinical laboratory services provides the services within the special hospital 24 hours a day:
 - <u>a.</u> Is able to provide clinical laboratory services when needed by the patients,

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- b. Obtains specimens for clinical laboratory services without transporting the patients from the special hospital's premises, and
- c. <u>Has the examination of the specimens performed by a clinical laboratory on the special hospital's premises or by arrangement with a clinical laboratory not on the premises;</u>
- 5. No change
- 6. No change
- 7. No change
 - a. No change
 - i. No change
 - ii. No change
 - b. No change
- 8. No change
- 9. No change
- 10. No change
 - a. No change
 - b. No change
 - c. No change
- 11. No change
 - a. No change
 - b. No change
- 12. No change

R9-10-219. Radiology Services and Diagnostic Imaging Services

- **A.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. A hospital that provides surgical services has radiology services and diagnostic imaging services on the hospital's premises to meet the needs of patients;
 - 4.<u>5.</u> No change
 - 5.6. A special hospital whose patients' diagnoses or treatment requires patients require radiology services and diagnostic imaging services is able to provide the radiology services and diagnostic imaging services or has a documented plan to provide the services to meet the needs of a patient when needed by the patients:
 - a. On the special hospital's premises, or
 - b. By arrangement with a radiology and diagnostic imaging facility that is not on the special hospital's premises.
- **B.** No change
 - 1. No change
 - a. No change
 - b. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - 2. No change
 - 3. A radiologist prepares a documented radiologic or diagnostic imaging patient report is prepared that includes:
 - a. No change
 - b. No change
 - c. A radiologist's physician's interpretation of the image;
 - d. No change
 - e. No change
 - 4. No change
 - 5. No change

R9-10-220. Intensive Care Services

- **A.** No change
- **B.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change

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- a. With a minimum of one registered nurse <u>assigned</u> for every three two patients; and
- b. According to an acuity plan as required in R9-10-208;
- 6. Each intensive care unit has a policy and procedure to ensure the needs of the patients are met at all times;
- 6.7. No change
- 7.8. No change
- 8.9. Nursing personnel assigned to an intensive care unit are A registered nurse qualified in advanced cardiopulmonary resuscitation specific to the age of the patients in the intensive care unit patient is responsible for the patient requiring intensive care services for purposes of performing resuscitation;
- 9.10.No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
- 10.11. No change
- C. No change

R9-10-222. Perinatal Services

- A. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - 7. No change
 - 8. No change
 - 9. No change
 - 10. No change
 - 11. No change
 - a. No change
 - b. No change
 - 12. No change
 - a. No change
 - b. No change
 - 13. No change
 - 14. No change
 - 15. No change
 - 16. A minimum of one registered nurse is on duty in a nursery at all times when there is a neonate in a the nursery except as provided in subsection (A)(17);
 - 17. A nursery occupied only by neonates receiving couplet care, who are placed in the nursery for the convenience of the mother and who do not require treatment as defined in this Article, is staffed by a licensed nurse;
 - 17.18. No change
 - 18.19. No change
- B. No change

R9-10-229. Infection Control

- **A.** No change
 - 1. No change
 - 2. No change
 - a. No change
 - i. No change
 - ii. No change

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- iii. No change
- iv. No change
- v. No change
- b. No change
 - i. No change
 - ii. No change
 - iii. No change
- e. That establish criteria for determining whether a medical staff member is at an increased risk of exposure to infectious pulmonary tuberculosis based on:
 - i. The level of risk in the area of the hospital premises where the medical staff member practices, and
 - ii. The work that the medical staff member performs; and
- d. That establish the frequency of tuberculosis screening for an individual determined to be at an increased risk of exposure;
- 3. No change
- 4. A tuberculosis screening is performed as follows:
 - a. For a personnel member, at least once every 12 months or more frequently if determined by an infection control risk assessment:
 - b. Except as required in subsection (A)(4)(c), for a medical staff member, at least once every 24 months; and
 - e. For a medical staff member at an increased risk of exposure based on the criteria in subsection (A)(2)(e), at the frequency required by the hospital's policies and procedures, but no less frequently than every 24 months;
- 4. The infection control risk assessment required in subsection (A)(3) includes a determination of the number of patients with infectious tuberculosis admitted to the hospital in each calendar year;
- 5. If a hospital with fewer than 200 inpatient beds admitted three or more patients with infectious active tuberculosis during the previous calendar year, or a hospital with 200 or more inpatient beds admitted six or more patients with infectious active tuberculosis during the previous calendar year, each personnel member or medical staff member of the hospital who does not have a documented history of a positive result from an approved test for tuberculosis:
 - a. Is evaluated for tuberculosis by March 30 of the current calendar year or before providing hospital services during the current calendar year, whichever is later; and
 - b. Provides:
 - i. Documentation of a negative result from an approved test for tuberculosis that includes the date and type of test:
 - ii. A statement written and dated by a physician, physician assistant, or registered nurse practitioner, other than the personnel member or medical staff member submitting the statement, indicating that the personnel member or medical staff member is free from infectious pulmonary tuberculosis; or
 - iii. An attestation that meets the requirements of R9-10-207(B)(3)(c):
- 6. By March 30 of each year, a personnel member or medical staff member with a documented history of a positive result from an approved test for tuberculosis provides a checklist completed by the personnel member or medical staff member indicating whether the personnel member or medical staff member is experiencing symptoms suggestive of tuberculosis:
- 7. If a personnel member or medical staff member with a documented history of a positive result from an approved test for tuberculosis experiences symptoms suggestive of tuberculosis, the personnel member or medical staff member is given a medical evaluation by a physician to determine whether the personnel member or medical staff member has active tuberculosis;
- 8. After a personnel member or medical staff member is exposed to infectious active tuberculosis, tuberculosis testing is performed according to the recommendations of the Centers for Disease Control and Prevention or the tuberculosis control officer;
- 5.9. No change
 - a. No change
 - b. No change
 - c. No change
- 6.10.No change
- 7.11.No change
 - a. No change
 - b. No change
 - c. No change
- 8.12.No change
- 9.13.No change
 - a. No change
 - b. No change
 - c. No change

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10.14. No change

- a. No change
- b. No change
- c. No change
- d. No change

B. No change

R9-10-230. Environmental Services

- 1. An individual providing environmental services who has the potential to transmit <u>pulmonary infectious</u> tuberculosis to patients as determined by the infection control risk assessment shall comply with the requirements <u>for a personnel member</u> in R9-10-206(3) <u>and (4) and R9-10-229(A)(5) through (8)</u>;
- 2. No change
 - a. No change
 - b. No change
- 3. No change
- 4. No change
- 5. No change
- 6. No change
 - a. No change
 - b. No change
 - c. No change
- 7. No change